REMARKS:

Amendments to claims

Claim 30 has been amended to incorporate the limitation that the drug is insulin-containing, this as defined in now-cancelled claim 31.

Further, the misspelling of "disease" has been corrected.

Claim rejections – 35 USC 103

Having regard to Applicants arguments forwarded with reply dated February 12, 2007 the Examiner states with reference to Gross et all (US patent 5,848,991) that "[i]t is clear from the disclosure in Gross that a wide and diverse variety of dosage regimes were contemplated, including a regime wherein the patient only receives treatment during periods of sleep".

Applicant respectfully disagrees. The argument that the drug delivery system of Gross allows Applicant's invention to be performed does not mean that the invention was contemplated by Gross. To the contrary, this finding can only be based on hindsight as Gross in fact teaches away from the present invention.

1. No disclosure of nighttime-only use in Gross et al

As also indicated in an earlier reply, Gross et al states that the disclosed drug delivery device "may comprise a microprocessor which controls the delivery such that the rate of delivery is varied during a 24 hour cycle as is necessary due to the differing requirements of drug dosage during periods of activity, inactivity and sleep, and taking account of the subject's requirements in relation to food intake", see column 4, lines 55-63. In other words, the Gross et al device may be in the form of an "advanced" drug delivery device providing the same programmability as the type of pumps mostly used for the treatment of Type 1 diabetes, e.g. as supplied by Medtronic.

In the next paragraph it is stated that "Alternatively (emphasis added), the subject may be provided with separate daytime and nighttime devices".

As follows from this, Gross et al teaches that instead of a more complex device comprising a microprocessor, the patient may be supplied with two separate devices each having a different electronic circuit for controlling the time and rate of drug delivery for daytime respectively nighttime use, this allowing a patient to wear a device during all 24 hours of the day, albeit in the form of one device during daytime and another device during nighttime.

Although theoretically such a system would allow the patient to wear only a device during nighttime, there is absolute no disclosure or hint to be found in Gross et all or in any other of the cited documents that would point the skilled person to such a use of the disclosed nighttime device. The forwarded argument can thus only be based on hindsight.

2. No disclosure of nighttime-only infusion of insulin in Gross et al

The same apply to the use of insulin in a nighttime-only regime as now claimed in amended claim 1.

In Gross et all it is disclosed that the device may be used to deliver a number of different drugs, see column 6, line 42 to column 7, line 21, and it may thus be argued that the Gross et al device may be used for periods of different length and for different infusion rates. However, there is no disclosure or teaching that any given type of drug should be infused during 7-9 hours and during a period of sleep. And most specifically, there is no disclosure or teaching that insulin should be infused during 7-9 hours and during a period of sleep only as defined in amended claim 30.

In contrast, applicant submits that when insulin is administered using a drug delivery device (i.e. in the form of a traditional type pump as provided by e.g. Medtronic) this is done solely for the treatment of patients suffering from diabetes Type 1 and thus for 24 hours. Treating diabetes patients with a body mounted drug delivery device with insulin during nighttime only is in contrast to all known regiments for the treatment of diabetes using a pump device and is, indeed, neither disclosed nor hinted at in Gross et al. The forwarded argument can thus only be based on hindsight.

In respect of the 7-9 hours limitation, the Examiner has cited Berner et al, paragraph 0126, however, this document is concerned with gastric delivery of calcium carbonate. Although Berner et al discloses that calcium carbonate may be delivered to the gastro-intestinal tract during 4-9 hours, applicant submits that this does not provide the skilled person with a teaching that insulin or any other drug should be administered to a patient during a period of 7-9 hours only using a skin mounted device.

That the present invention as defined in amended claim 30 represents a special selection of properties and ranges (i.e. delivery of insulin to a patient using a pump device during nighttime only) providing special advantages associated with the selected properties and ranges is discussed in applicants reply dated April 17, 2006 to which reference is made.

Conclusion

In conclusion, Gross et all alone or in view of any of the references on file fails to make obvious to the skilled person a method as defined in amended claim 30.

All further claims are dependent upon an independent claim.

In view of the above, applicants respectfully submit that all claims are in condition for allowance.

The Commissioner is hereby authorized to charge any fees, including fees for extensions of time, in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. Should the Examiner have any questions or concerns, she should feel free to contact the applicants' attorney to discuss them.

Respectfully submitted,

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/Marc A. Began, Reg No. 48,829/
Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800